# David Gortler

Senior Advisor to the FDA Commissioner (Science, Drug Safety and FDA Policy) at Department of Health and Human Services (/org/u-s-department-of-health-and-human-services)

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Dr. David Gortler is a member of the FDA's Senior Executive Leadership Team. He serves as Senior Advisor to the FDA commissioner on matters of drug safety (clinical and non-clinical), FDA science policy and FDA regulatory affairs.

Dr. Gortler's Executive Schedule appointment was made during the early stages (first wave) of 2019-nCoV pandemic. The 2019-nCoV pandemic was the FDA's most critical and scientifically ambitious emergency vaccine and emergency drug authorization approval challenges in modern public health history.

As a drug safety expert hired to advise the FDA commissioner, Dr. Gortler was also tasked to assist the FDA Commissioner and the FDA with assuring quality control of overseas drug supply, USA on-shoring of critical pharmaceuticals/ API, recommendations on drug supply chain dynamics, FDA policy implementation, new drug safety initiatives, emergency drug and vaccine development and various other urgent regulatory action items for the 2019-nCoV pandemic.

He is a former Yale University and Georgetown University didactic professor of pharmacology and biotechnology with over a decade of academic experience, on top of nearly two decades of experience in drug development. He had previously served as an FDA medical officer/senior medical analyst, and was personally in charge of approving new drugs and labeling changes within the FDA's Center of Drug Evaluation and Research (CDER). Prior to that, Dr. Gortler served as an investigational medicine research scientist and clinical trial principal lead at Pfizer Inc., as well as a scientific and drug safety advisor to Merck & Co., in addition to several other major pharmaceutical and medical device developers and manufacturers. He has also worked as an FDA subject matter expert at <a href=http://www.FormerFDA.com</a>

To date, Dr. Gortler has over two decades of hands-on, state-of-the-art knowledge and experience in drug development, drug safety, device safety, FDA regulatory affairs, pharmacovigilance, AERS/ FAERS/ MAUDE and VARES database research and analysis. His experiences and perspectives cover the complete triad of industry, academia and federal regulation. He additionally has experience in complex scientific problem solving and managing large-scale critical FDA/regulatory projects, as well as managing scientists and other employees in both the private sector and the federal government. Dr. Gortler has formal academic training in both clinical and basic science pharmacology, a postdoctoral basic science research fellowship in vascular medicine/molecular biology from The Yale University School of Medicine, and a clinical residency through The Columbia - New York Presbyterian hospital system.

He has additional specialized experience as an FDA and healthcare policy advisor, having worked under and/or advised multiple US Presidents and/or Presidential campaigns (W.Bush, Obama, Cruz, Trump).

Dr. Gortler also personally conceptualized and founded the world's first "analytical pharmacy" with its mission to assure quality control by independently analyzing imported, overseas finished drug products. Dr. Gortler's start-up, novel analytical pharmacy was responsible for the worldwide FDA recalls of ranitidine and multiple ARBs, (including valsartan, irbesartan, losartan) due to

cancer-causing contamination of nitrosamine, N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) impurities. In the end, the publication of, and the notifying the FDA on these findings, necessitated the worldwide recall of more than 100 FDA-approved products over a two-year period in 2018 - 2019.

Dr. David Gortler is an expert in drug development, drug safety, pharmacovigilance and FDA regulatory science, and has been quoted by the lay press well over 100 times prior to his most recent FDA service, within his areas of expertise.

Dr. David Gortler is the first pharmacist/pharmacologist to ever be appointed to serve on the FDA Senior Executive Leadership Team as Senior Advisor to an FDA commissioner.

Company start date: March 2020

Role start date: March 2020

Location: 10903 New Hampshire Avenue, Silver Spring, United States

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**Manager**

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